

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
Rosen et al.

Docket No.: PF596P1N

Application No.: 10/602,727

Confirmation No.: 1552

Filed: June 25, 2003

Art Unit: 1645

For: Antibodies Against Protective Antigen

Examiner: Patricia A. Duffy

**APPLICATION FOR PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. § 1.705(b)**

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby request reconsideration of the 400 days of Patent Term Adjustment (PTA) indicated on Form PTOL-85 mailed with the Notice of Allowance on December 10, 2008. For the reasons set forth below, Applicants submit that the total PTA due under 35 U.S.C. § 154(b) should instead be 594 days. In particular, Applicants believe that an apparent reduction for the filing of an Information Disclosure Statement (IDS) four days after a response is not proper, as the IDS filing did not constitute a failure to engage in reasonable efforts to conclude prosecution of the application. Applicants also believe that the PAIR system incorrectly treated a Notice to Comply as a proper response under 35 U.S.C. § 132 to Applicants' July 7, 2006 reply.

This application is being timely made, as it is being submitted concurrently with the issue fee payment. The requirements of 37 C.F.R. § 1.705(b)(1) are satisfied by the Fee Transmittal Sheet enclosed herewith, authorizing payment of the fee set forth in 37 C.F.R. § 1.18(e) and any other fees that may be due. The requirements of 37 C.F.R. § 1.705(b)(2) are satisfied by the following Statement of Facts, as supplemented by the attached Exhibit.

STATEMENT OF FACTS

1. The application was filed on June 25, 2003, and is thus eligible for PTA under 35 U.S.C. § 154.
2. The instant application is not subject to a terminal disclaimer.
3. A Notice to File Missing Parts was mailed October 9, 2003. Applicants timely responded on December 9, 2003.
4. Although the instant application was filed on June 25, 2003, the Office failed to initially act on the application within the 14 month permitted time frame allowed under 35 U.S.C. § 154(b)(1)(A)(i). In particular, an office action was not mailed until March 7, 2006. Thus, Patentees are entitled to a PTA of 559 days due to the Patent Office's delay from the day after the date fourteen months after the application was filed (August 26, 2004) to the date of mailing of the first notification under 35 U.S.C. 132 (March 7, 2006). *See* 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. §§ 1.702(a)(1) & 1.703(a)(1).
5. A complete reply to the March 7, 2006 office action was filed on July 7, 2006 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 30 days from the day after the date three months after the mailing of the office action (June 8, 2006) to the date of the response (July 7, 2006).
6. An Information Disclosure Statement (IDS) was filed on July 11, 2006. According to the PAIR system, a PTA reduction of 4 days was applied as a result of this filing. *See* PAIR Patent Term Adjustment History (Exhibit A). For the reasons discussed below, Applicants do not believe that this PTA reduction is appropriate.
7. A Notice to Comply requesting a new Sequence Listing was mailed on October 13, 2006. While the PAIR system appears to indicate that this Notice is being treated as a response to Applicants' July 7, 2006 reply, as noted below, Applicants disagree that this Notice is a proper response under 35 U.S.C. § 132 in compliance with 35 U.S.C. § 154(b)(1)(A)(ii) and 37 C.F.R. §§ 1.702(a)(2) & 1.703(a)(2).

8. A response to the Notice to Comply was filed on January 16, 2007, with a petition for an extension of time of two months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 3 days from the day after the date three months after the mailing of the Notice (January 14, 2007) to the date of the response (January 16, 2007).

9. A non-final office action responsive to Applicants' July 7, 2006 reply was mailed on July 19, 2007. However, the Office failed to respond under 35 U.S.C. § 154(b)(1)(A)(ii) within the 4 month permitted time frame after Applicants' July 7, 2006 reply. Thus, Patentees are entitled to a PTA of 254 days due to the Patent Office's delay from the day after the date four months after date the reply was filed (November 8, 2006) and ending on the date of mailing of the non-final office action under 35 U.S.C. 132 (July 19, 2007). *See* 37 C.F.R. §§ 1.702(a)(2) & 1.703(a)(2). Applicants note that the PAIR system apparently treated the Notice to Comply mailed October 13, 2006 as a response under 35 U.S.C. § 132 to Applicants' July 7, 2006 reply sufficient to end the four month response period set forth in 35 U.S.C. § 154(b)(1)(A)(ii) and 37 C.F.R. §§ 1.702(a)(2) & 1.703(a)(2). Applicants disagree as noted below, but even assuming *arguendo* that is the case, the Office still failed to respond under 35 U.S.C. § 154(b)(1)(A)(ii) within the 4 month permitted time frame after the date on which the reply to the Notice to Comply was filed (January 16, 2007). Thus, as shown in the PAIR system (Exhibit A), Applicants would at least be entitled to a PTA of 64 days due to the Patent Office's delay from the day after the date four months after date the reply was filed (May 17, 2007) and ending on the date of mailing of the non-final office action under 35 U.S.C. § 132 (July 19, 2007). *See* 37 C.F.R. §§ 1.702(a)(2) & 1.703(a)(2).

10. A response to the July 19, 2007 non-final office action was filed on January 22, 2008 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 95 days from the day after the date three months after the mailing of the office action (October 20, 2007) to the date of the response (January 22, 2008).

11. A final office action was mailed on April 28, 2008.

12. A response to the final office action was filed on October 27, 2008 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 91 days from the day after the date three months after the mailing of the office action (July 29, 2008) to the date of the response (October 27, 2008).

13. On December 10, 2008, a Notice of Allowance was mailed. Together with the Notice of Allowance, a Determination of Patent Term Adjustment (Form PTOL-85) under 35 U.S.C. § 154(b) was mailed indicating a PTA of 400 days.

14. Other than the circumstances described above, there have been no circumstances that could reasonably be construed as a failure to engage in reasonable efforts to conclude processing or examination of this application.

ARGUMENT

Applicants respectfully assert that the PTA calculation is incorrect under 35 U.S.C. § 154(b) due to (1) the apparent PTA reduction of 4 days associated with the IDS filed on July 11, 2006; and (2) the apparent incorrect treatment in the PAIR system of the Notice to Comply mailed October 13, 2006 as responsive to Applicants' July 7, 2006 reply.

With respect to the IDS filing of July 11, 2006, Applicants do not believe any PTA reduction is appropriate under 35 U.S.C. § 154(b)(2) or 37 C.F.R. § 1.704. The reply filed July 7, 2006 was a complete reply to the office action of March 7, 2006, and thus the IDS was not a supplemental paper as contemplated by 37 C.F.R. § 1.704(c)(8). Additionally, Applicants note that the filing of the IDS on July 11, 2006 could not have delayed the Examiner's consideration of Applicants' reply or the preparation of a response under 35 U.S.C. § 132, as the July 7, 2006 filing was not forwarded to the Examiner until July 11, 2006, the same day on which the IDS was filed. *See Exhibit A (07-11-2006, Date Forwarded to Examiner)*. Accordingly, Applicants believe that the 4 day PTA reduction shown in PAIR (*see Exhibit A*) is not appropriate under 35 U.S.C. § 154(b)(2), since Applicants did not fail to engage in reasonable efforts to conclude processing or examination of the application.

With respect to the Notice to Comply mailed October 13, 2006, the PAIR system

apparently treated the Notice as a timely response by the Office under 35 U.S.C. § 132 to Applicants' July 7, 2006 reply. The PAIR system thus only calculated PTA for the delay between the response to the Notice to Comply and the non-final rejection mailed July 19, 2007 (shown as 64 days on Exhibit A). Applicants respectfully disagree that the Notice to Comply is a proper response under 35 U.S.C. § 154(b)(1)(A)(ii) and 37 C.F.R. §§ 1.702(a)(2) & 1.703(a)(2), as it is not responsive to Applicants' July 7, 2006 reply. Pursuant to 35 U.S.C. § 154(b)(1)(A)(ii), the Office must "respond to a reply under section 132 ... within 4 months after the date on which the reply was filed." 35 U.S.C. § 132 states that "if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined." In the instant case, an office action was mailed to Applicants on March 7, 2006, and after receiving the action, Applicants persisted by filing a reply on July 7, 2006. However, the next action received by Applicants was the Notice to Comply mailed October 13, 2006, which was not responsive to Applicants' reply. Applicants did not receive reexamination of the application by the Office pursuant to 35 U.S.C. § 132 in response to the claim amendments, election, and request for rejoinder made in the July 7, 2006 reply until the non-final rejection mailed July 19, 2007, a delay of 254 days beyond the four months provided to the Office by 35 U.S.C. § 154(b)(1)(A)(ii). *Cf. Wyeth v. Dudas*, 580 F.Supp.2d. 138, 139 (D. DC 2008) (noting that 35 U.S.C. § 154(b)(1)(A) provides a guarantee of prompt PTO response by providing the Office a deadline of "four months to respond to a reply," not merely issue a requirement unrelated to Applicants' reply within four months). Accordingly, Applicants respectfully assert that the calculation of 64 days of PTA for the period ended by the July 19, 2007 office action should instead be 254 days as noted above.

Applicants respectfully request that the PTA for the instant application be reconsidered and corrected in light of the facts and arguments above. If any further information is required, please contact the undersigned at the number listed below. Please charge any additional fees due

in connection with the filing of this paper, or credit any overpayment, to Deposit Account No. 08-3425.

Dated: March 6, 2009

Respectfully submitted,

/Mark J. Hyman/

Mark J. Hyman

Registration No.: 46,789

HUMAN GENOME SCIENCES, INC.

Intellectual Property Dept.

14200 Shady Grove Road

Rockville, Maryland 20850

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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/602,727

Filing or 371(c) Date:	06-25-2003	USPTO Delay (PTO) Delay (days):	623
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	223
Post-Issue Petitions (days):	+0	Total PTA (days):	400
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
12-10-2008	Mail Notice of Allowance		
12-09-2008	Document Verification		
12-09-2008	Notice of Allowance Data Verification Completed		
11-26-2008	Case Docketed to Examiner in GAU		
11-24-2008	Examiner's Amendment Communication		
11-07-2008	Date Forwarded to Examiner		
10-27-2008	Amendment/Argument after Notice of Appeal		
10-27-2008	Notice of Appeal Filed		91
10-27-2008	Request for Extension of Time - Granted		⌘
04-28-2008	Mail Final Rejection (PTOL - 326)		⌘
04-25-2008	Final Rejection		
02-21-2008	Date Forwarded to Examiner		
01-22-2008	Response after Non-Final Action		95
01-22-2008	Request for Extension of Time - Granted		⌘
07-19-2007	Mail Non-Final Rejection	64	
07-09-2007	Non-Final Rejection	⌘	
05-02-2007	Date Forwarded to Examiner	⌘	
01-16-2007	Response to a Letter to Comply with the Sequence Rules		3
01-16-2007	Request for Extension of Time - Granted		⌘
01-25-2007	CRF Is Good Technically / Entered into Database		⌘
10-13-2006	Mail Letter Requiring CRF (Unreadable, Non-Compliant, Not Submitted)		⌘
09-29-2006	CRF Diskette Unreadable / Did Not Comply / Required but Not Submitted		
07-11-2006	Information Disclosure Statement considered		
07-11-2006	Reference capture on IDS		
07-11-2006	Information Disclosure Statement (IDS) Filed		4
07-11-2006	Information Disclosure Statement (IDS) Filed		
07-11-2006	Date Forwarded to Examiner		⌘
07-07-2006	Response to Election / Restriction Filed		30
07-07-2006	Request for Extension of Time - Granted		⌘
03-07-2006	Mail Restriction Requirement	559	
03-03-2006	Requirement for Restriction / Election	⌘	
12-01-2005	IFW TSS Processing by Tech Center Complete	⌘	
05-24-2005	Miscellaneous Incoming Letter	⌘	
06-25-2004	Receipt of all Acknowledgement Letters	⌘	

05-03-2004	Receipt of Acknowledgment Letter	✦
01-16-2004	Case Docketed to Examiner in GAU	✦
12-31-2003	Application Return from OIPE	✦
12-31-2003	Application Return TO OIPE	✦
12-30-2003	Application Dispatched from OIPE	✦
12-31-2003	Application Is Now Complete	✦
12-09-2003	Additional Application Filing Fees	✦
12-09-2003	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	✦
11-12-2003	Receipt of Acknowledgment Letter	✦
10-27-2003	Agency Referral Letter Mailed	✦
10-09-2003	Agency Referral Letter Mailed	✦
10-09-2003	Agency Referral Letter Mailed	✦
10-09-2003	Notice Mailed--Application Incomplete--Filing Date Assigned	✦
06-25-2003	PGPubs nonPub Request	✦
10-07-2003	Referred by L&R for Third-Level Security Review. Agency Referral Letter Generated	✦
10-07-2003	Referred by L&R for Third-Level Security Review. Agency Referral Letter Generated	✦
10-07-2003	Referred by L&R for Third-Level Security Review. Agency Referral Letter Generated	✦
10-07-2003	Referred to Level 2 (LARS) by OIPE CSR	✦
08-11-2003	IFW Scan & PACR Auto Security Review	✦
08-05-2003	CRF Is Good Technically / Entered into Database	✦
06-25-2003	CRF Disk Has Been Received by Preexam / Group / PCT	✦
06-25-2003	Initial Exam Team nn	✦

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